REMARKS

The applicants have studied the Office Action dated July 5, 2002, and have made amendments to the claims. By virtue of this amendment, no claims have been canceled, claims 47-54 have been added, and claims 1, 8-10, 12-13, 15-22, 27-31, 42-44, and 46 have been amended; thus, claims 1-54 are pending. It is submitted that the application, as amended, is in condition for allowance. Reconsideration and allowance of all of the claims in view of the above amendments and the following remarks are respectfully requested.

The applicants wish to thank the Examiner for her time in the November 15, 2002 interview with the applicants' representatives. The applicants have amended the claims and have provided the following remarks in accordance with the discussions between the Examiner and the undersigned. The applicants respectfully submit that the application should now be in condition for allowance. If the Examiner has any further questions or comments, the Examiner is requested to call the undersigned to advance the prosecution of the application in a follow-up interview.

Claim 12 was rejected under 35 U.S.C. § 112, first paragraph as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. This rejection is respectfully traversed.

Claim 12 was rejected for reciting "selection of...one of the...menu items causes the drive mechanism to reverse direction," as this limitation was not found by the Examiner in the written description. However, the applicants point out that there is support for this limitation on page 10, lines 9-11 and page 29, line 22 to page 30, line 3. On page 10, lines 9-11, the written description recites that the drive mechanism includes a plunger slider. Additionally, on page 29, line 22 to page 30, line 3, the written description recites that when Rewind is selected from the Prime Menu, the information displayed on the infusion device guides the user through a series of steps to rewind the plunger slider, install a new reservoir, and prime the infusion system. Thus, the specification clearly discloses the selection of one of the menu items to cause the drive mechanism to reverse direction, as recited in claim 12.

Accordingly, it is respectfully submitted that the rejection of claim 12 under 35 U.S.C. § 112, first paragraph should be withdrawn.

Claims 1, 3-8, and 15-46 were rejected under 35 U.S.C. § 102(b) as being anticipated by Peterson et al. This rejection is respectfully traversed.

Embodiments of the present invention are directed to a portable infusion system that is programmable by an individual for delivering fluid from a reservoir into a user. The infusion system includes a drive mechanism that forces the fluid out of the reservoir, an input device that accepts one or more inputs, a processor that uses the inputs to modify one or more control parameters to control the drive mechanism, and a display that receives information from the processor and visually displays one or more screens containing the information. One or more of the screens is a select screen that includes at least two menu items, and the input device is used to select one menu item from amongst the at least two menu items. Selection of one of the at least two menu items causes the display to show at least another one of the screens that is a set screen. The set screen includes a plurality of control parameters associated with the selected menu item, and guides the individual through sequential steps for programming the plurality of control associated with the selected menu item. The input device is used to program the plurality of control parameters associated with the selected menu item from the set screen. Thus, the portable infusion system provides a menu structure for easily accessing and modifying control parameters associated with particular functions to control the drive mechanism.

Claim 1 and its dependent claims 3-8 and 15-41 recite "a set screen including a plurality of control parameters associated with the selected menu item, and further wherein the set screen guides the individual through sequential steps for programming the plurality of control parameters associated with the selected menu item" (emphasis added). Claim 42, as well as claim 43 and its dependent claims 44-46, recite similar language. The Peterson et al. reference fails to disclose, teach, or suggest an infusion system including a set screen that guides the user through sequential

steps for programming a plurality of control parameters associated with a selected menu item, as recited in the claims.

The Peterson et al. reference is directed to a reprogrammable drug pump. The pump includes various function keys, such as a NEXT SCREEN key to move through screens, an ENTER/CLEAR key, UP ARROW and DOWN ARROW keys, a PRIME key to prime the pump, a START/STOP key for starting and stopping the pump, and a DOSE key to manually administer an additional dose of medication to a patient (col. 25, lines 47-67). As noted by the Examiner, the pump also includes a display that shows one or more screens containing information, and one of the screens includes at least two menu items. For example, the UP ARROW and DOWN ARROW keys may be utilized to page through what is displayed on the screen, respond to YES/NO questions, page through numeric values, and/or display desired values (col. 25, lines 54-58). However, the Peterson et al. reference does not disclose that selection of one of the menu items causes the display to show "a set screen including a plurality of control parameters associated with the selected menu item," as recited in the claims (emphasis added). Instead, in the Peterson et al. reference, the pump displays a set screen for programming a single control parameter, such as a YES/NO response or a single numeric value. Further, the Peterson et al. reference does not disclose that "the set screen guides the individual through sequential steps for programming the plurality of control parameters associated with the selected menu item," as recited in the claims. Therefore, the Peterson et al. reference fails to disclose, teach, or suggest a portable infusion system including a set screen that has a plurality of control parameters associated with a selected menu item and that guides an individual through sequential steps for programming the plurality of control parameters associated with the selected menu item, as in the claimed embodiments.

Claim 27 is further distinguished over the Peterson et al. reference by reciting "selection of another one of the...menu items causes the display to show...one or more information screens to guide the individual through sequential steps to prime the infusion system" (emphasis added). As noted by the Examiner, the pump in the Peterson et al. reference includes a PRIME key to run a pump prime program to prime the pump (col. 25, lines 59-60). However, the Peterson et al.

reference does not disclose that the pump displays any information screens to guide the user through the sequential steps necessary for priming the infusion system. Thus, the Peterson et al. reference fails to disclose, teach, or suggest a portable infusion system including "one or more information screens to guide the individual through sequential steps to prime the infusion system," as recited in claim 27.

Claims 28 and 29 are further distinguished over the Peterson et al. reference by reciting "the menu item that is highlighted by default is dependent on a function that the infusion system is performing when the select screen is initially displayed." As noted by the Examiner, the pump in the Peterson et al. reference includes UP ARROW and DOWN ARROW keys to page through what is displayed on the screen with a highlight bar (col. 25, lines 54-58). However, the Peterson et al. reference does not disclose that any particular menu item is highlighted by default when the menu is initially displayed. Therefore, the Peterson et al. reference additionally fails to disclose, teach, or suggest a portable infusion system including a select screen with at least two menu items, wherein "one of the...menu items is highlighted by default when the select screen is initially displayed, and the menu item that is highlighted by default is dependent on a function that the infusion system is performing when the select screen is initially displayed," as recited in claims 28 and 29.

For these reasons, the applicants respectfully request withdrawal of the rejection of claims 1, 3-8, and 15-46 under 35 U.S.C. § 102(b) as these claims are not anticipated by Peterson et al.

Claims 1 and 2 were rejected under 35 U.S.C. § 102(e) as being anticipated by DeLaHuerga. This rejection is respectfully traversed.

The DeLaHuerga reference is directed to an information system network that includes personal computers or computer terminals, network devices such as databases and servers, a laboratory system or server, various bedside treatment devices such as IV infusion pumps, patient monitoring devices, a pharmacy system, a security verification system, a billing system, a patient historical records system, and a unit dose medication dispenser. Although the DeLaHuerga

reference describes a computer terminal screen with a physician's personal menu of application icons, such as an Internet icon, the computer terminal is distinctly separate from the IV infusion pump. The disclosed menu is displayed on the computer terminal, not on the pump. And any menu item selected on the computer terminal does not cause a set screen to be displayed on the pump for programming any control parameters of the pump. Therefore, the DeLaHuerga reference fails to disclose, teach, or suggest an infusion system including a display that shows a select screen having at least two menu items, wherein selection of one of the menu items causes the display to show a set screen including a plurality of control parameters associated with the selected menu item, and further wherein the set screen guides the individual through sequential steps for programming the plurality of control parameters associated with the selected menu item, as recited in the claims.

Claim 2 is further distinguished over the DeLaHuerga reference by reciting "the processor runs energy software that changes the display to a Blank Screen after a Time-Out delay has expired." As noted by the Examiner, the DeLaHuerga reference describes a computer terminal display that is blanked if the computer terminal does not receive a recommitment response signal. Again however, the computer terminal is distinctly separate from the IV infusion pump, and the disclosed display that is blanked is on the computer terminal, not on the pump. Thus, the DeLaHuerga reference fails to disclose, teach, or suggest an infusion system including a processor that runs energy software to change the display to a blank screen after a time-out delay has expired, as recited in claim 2.

Accordingly, the applicants respectfully request withdrawal of the rejection of claims 1 and 2 under 35 U.S.C. § 102(e) as these claims are not anticipated by DeLaHuerga.

Claims 1, 7, 9, 10, and 20 were rejected under 35 U.S.C. § 102(b) as being anticipated by Coutre et al. This rejection is respectfully traversed.

The Coutre et al. reference describes a pharmacy management system for generating a label in bar coded and human readable format that is placed on a container of an intravenous

solution made by the pharmacy. The label is read by a bar code reader, and all the information in the label, including delivery instructions for the intravenous solution, is transferred to an infusion pumping system. The infusion pumping system then delivers the intravenous solution to a patient in accordance with the instructions (col. 3, line 47 to col. 4, line 12). The Coutre et al. reference discloses that the pharmacy management system takes an operator through a series of screens and menus to include the appropriate delivery instructions for the infusion pumping system in the bar coded label (col. 4, lines 29-43). However, the disclosed screens and menus are displayed on a computer, not on the infusion pump. Further, any menu item selected on the computer does not cause a set screen to be displayed on the pump for programming any control parameters of the pump. Thus, the Coutre et al. reference fails to disclose, teach, or suggest an infusion system including a display that shows a select screen having at least two menu items, wherein selection of one of the menu items causes the display to show a set screen including a plurality of control parameters associated with the selected menu item, and further wherein the set screen guides the individual through sequential steps for programming the plurality of control parameters associated with the selected menu item, as recited in the claims.

Claims 7 and 20 are further distinguished over the Coutre et al. reference by reciting a means to store, and a screen to select, an insulin type. Although the Coutre et al. reference discloses that the rate of flow of insulin may be altered in response to the patient's blood sugar level (col. 15, lines 41-45), the Coutre et al. reference does not disclose storing or selecting an insulin type. Therefore, the Coutre et al. reference fails to disclose, teach, or suggest an infusion system including a means to store, or a screen to select, an insulin type, as recited in claims 7 and 20.

Claim 9 is further distinguished over the Coutre et al. reference by reciting "selection of another one of the...menu items causes the infusion system to reset the control parameters to factory default values." Similarly, claim 10 is further distinguished over the Coutre et al. reference by reciting "to reset control parameters to values set by a health care professional." The Coutre et al. reference discloses that default data is placed into the system for creating labels, but the data may be changed by the user (col. 5, lines 60-67). Again however, the disclosed default

data is provided on the computer, not on the infusion pump. Furthermore, the Coutre et al. reference does not describe any menu option for resetting the control parameters, either to factory default values or values set by a health care professional. Thus, the Coutre et al. reference fails to disclose, teach, or suggest that selection of a menu item causes the infusion system to reset the control parameters either to factory default values or values set by a health care professional, as recited in claims 9 and 10.

For these reasons, the applicants respectfully request withdrawal of the rejection of claims 1, 7, 9, 10, and 20 under 35 U.S.C. § 102(b) as these claims are not anticipated by Coutre et al.

Claims 1 and 11 were rejected under 35 U.S.C. § 102(e) as being anticipated by Say et al. This rejection is respectfully traversed.

The Say et al. reference is directed to an analyte monitoring device for the in vivo monitoring of an analyte, such as glucose or lactate. The monitoring device includes a keypad for providing input to and initiating functions on the monitoring device (col. 53, lines 15-25). The monitoring device may also include a touch screen display (col. 53, lines 26-32). However, the disclosed keypad and screen are on the monitoring device, not an infusion pump. While the Say et al. reference discloses the use of a drug administration system such as an external infusion pump in conjunction with the analyte monitoring device, the infusion pump is separate from the monitoring device. Additionally, the Say et al. reference teaches a closed loop system in which the drug administration system administers the drug in response to data received from the analyte monitoring device, rather than in response to programming by an individual (col. 54, lines 15-61). Thus, the Say et al. reference does not describe any programming of control parameters on an infusion pump by an individual, and in particular, does not disclose, teach, or suggest an infusion system including a display that shows a select screen having at least two menu items, wherein selection of one of the menu items causes the display to show a set screen including a plurality of control parameters associated with the selected menu item, and further wherein the set screen guides the individual through sequential steps for programming the plurality of control parameters associated with the selected menu item, as recited in the claims.

Claim 11 is further distinguished over the Say et al. reference by reciting "an alarm wherein the alarm intensity changes with time." The Say et al. reference discloses that the volume of the alarm increases over time until the alarm is deactivated (col. 46, lines 21-23). Again however, the disclosed alarm is on the analyte monitoring device, not an infusion pump. Therefore, the Say et al. reference fails to disclose, teach, or suggest an infusion system including an alarm that changes its intensity with time, as recited in claim 11.

Accordingly, the applicants respectfully request withdrawal of the rejection of claims 1 and 11 under 35 U.S.C. § 102(e) as these claims are not anticipated by Say et al.

Claims 1 and 12 were rejected under 35 U.S.C. § 102(b) as being anticipated by Lundquist et al. This rejection is respectfully traversed.

The Lundquist et al. reference discloses a retroperfusion, retroinfusion control apparatus that includes a positive displacement pump. An initial flow rate for the pump can be set by pressing a menu button, which causes a menu screen to be displayed. The up and down keys can then be used to select the correct value for the flow rate. Once the correct value has been set, the menu button is pressed again to enter the new flow rate and execute the flow adjustment. However, the Lundquist et al. reference does not disclose that selection of one of the menu items causes the display to show "a set screen including a plurality of control parameters associated with the selected menu item," as recited in the claims (emphasis added). Instead, in the Lundquist et al. reference, the pump displays a set screen for programming a single control parameter, such as the flow rate. Further, the Lundquist et al. reference does not disclose that "the set screen guides the individual through sequential steps for programming the plurality of control parameters associated with the selected menu item," as recited in the claims. Therefore, the Lundquist et al. reference fails to disclose, teach, or suggest a portable infusion system including a set screen that has a plurality of control parameters associated with a selected menu item and that guides an individual through sequential steps for programming the plurality of control parameters associated with the selected menu item, as in the claimed embodiments.

Claim 12 is further distinguished over the Lundquist et al. reference by reciting "selection of another one of the...menu items causes the drive mechanism to reverse direction." The Lundquist et al. reference discloses that the motor operates in forward and then in reverse (col. 10, lines 41-48); however, the motor does not operate in reverse in response to selection of a menu item. Instead, the motor operates in forward and then in reverse in response to the use of a lookup table and based upon the sensed heart rate input and the delivery setting inserted by the physician into the pump (col. 10, lines 48-58). Therefore, the Lundquist et al. reference fails to disclose, teach, or suggest an infusion system in which selection of a menu item causes the drive mechanism to reverse direction, as recited in claim 12.

For these reasons, the applicants respectfully request withdrawal of the rejection of claims 1 and 12 under 35 U.S.C. § 102(b) as these claims are not anticipated by Lundquist et al.

Claims 1 and 13 were rejected under 35 U.S.C. § 102(e) as being anticipated by Benkowski et al. This rejection is respectfully traversed.

The Benkowski et al. reference is directed to an implantable blood pump. The Benkowski et al. reference discloses an operator interface to change pump parameters, such as pump speed, alarm thresholds, and excess suction parameters (col. 15, lines 44-47). However, the disclosed operator interface is displayed on a separate computer or clinical data acquisition system, not the pump. The pump itself has a user interface including a display and two keypad switches to perform the functions of alarm silence and display scroll (col. 12, line 38 to col. 13, line 67). However, the disclosed user interface does not allow the patient to program control parameters on the pump. Instead, the patient is only able to view status and error messages on the pump. Thus, the Benkowski et al. reference fails to disclose, teach, or suggest an infusion system including a display that shows a select screen having at least two menu items, wherein selection of one of the menu items causes the display to show a set screen including a plurality of control parameters associated with the selected menu item, and further wherein the set screen guides the

individual through sequential steps for programming the plurality of control parameters associated with the selected menu item, as recited in the claims.

Claim 13 is further distinguished over the Benkowski et al. reference by reciting "selection of another one of the...menu items causes the infusion system to begin a selftest." The Benkowski et al. reference discloses that the pump is programmed with a selftest routine; however, the selftest routine is not executed in response to selection of a menu item. Instead, the selftest routine is executed upon application of power to check components of the pump (col. 5, lines 51-53). Therefore, the Benkowski et al. reference fails to disclose, teach, or suggest an infusion system in which selection of a menu item causes the infusion system to begin a selftest, as recited in claim 13.

Accordingly, the applicants respectfully request withdrawal of the rejection of claims 1 and 13 under 35 U.S.C. § 102(e) as these claims are not anticipated by Benkowski et al.

Claim 14 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Peterson et al. in view of Havel. This rejection is respectfully traversed.

Claim 14 depends from claim 1. Thus, it is respectfully submitted that claim 14 is patentable over the Peterson et al. reference for the reasons discussed above with respect to claim 1. Further, the Havel reference does not make up for the deficiencies of the Peterson et al. reference. The Havel reference is directed to a variable color digital display for emphasizing the position of a decimal point. The display illuminates all digits that precede the decimal point in a first color and all digits that follow the decimal point in a second color. However, the Havel reference includes no disclosure of an infusion system or modifying control parameters on the infusion system through a select screen and a set screen, as in the claimed embodiments.

Furthermore, it is respectfully submitted that it would not have been obvious to combine the Peterson et al. and Havel references, as suggested by the Examiner. To establish a *prima facie* case of obviousness, there must be some teaching or suggestion to modify a reference or to

combine references, and this teaching or suggestion must be found in the prior art, not in the applicant's disclosure. MPEP §§ 2142, 2143. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the reference expressly or impliedly teaches or suggests the desirability of the combination. In re Mills, 916 F.2d 680, 682, 16 USPQ2d 1430, 1432 (Fed. Cir. 1990); Ex parte Clapp, 227 USPQ 972, 973 (Bd. App. 1985); MPEP §§ 2142, 2143.01.

The cited references, Peterson et al. and Havel, fail to meet the basic requirements for a finding of obviousness. There is no teaching or suggestion in the references to modify or combine the devices disclosed therein in the direction of the presently claimed invention, nor is there any teaching or suggestion whatsoever of the desirability of such modification or combination (i.e., combining a programmable drug pump with a variable color digital display). Thus, it is respectfully submitted that it would not have been obvious to combine the references as suggested by the Examiner.

For these reasons, withdrawal of the rejection of claim 14 under 35 U.S.C. § 103(a) is respectfully requested.

New dependent claims 47-54 have been added. The applicants submit that support for the new claims is found throughout the specification, including on page 17, lines 18-22; page 18, line 19 to page 19, line 5; page 22, line 24 to page 23, line 4; and page 25, line 14 to page 28, line 23. Thus, no new matter has been added. The applicants further submit that new claims 47-54, which depend directly or indirectly from independent claim 1, further define the applicants' invention, and are allowable over the cited art for the reasons discussed above with respect to claim 1. Accordingly, allowance of new claims 47-54 is respectfully requested.

In view of the foregoing, it is respectfully submitted that the application and all of the claims are in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**."

If, for any reason, the Examiner finds that the application is other than in condition for allowance and believes that a telephone interview would advance the prosecution of the application, the Examiner is invited to call the undersigned attorney at (818) 576-5291.

Respectfully submitted,

Date: November 15, 2007

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1, 8-10, 12-13, 15-22, 27-31, 42-44, and 46 have been amended, and new claims 47-54 have been added, as follows:

1. (Amended) A portable infusion system that is programmable by an individual for delivering fluid from a reservoir into a user, the infusion system comprising:

a drive mechanism that forces the fluid out of the reservoir;

an input device that accepts one or more inputs;

a processor that uses one or more of the one or more inputs to modify one or more control parameters to control the drive mechanism; and

a display that receives information from the processor and visually displays one or more screens containing the information,

wherein at least one of the one or more screens is a select screen that includes [a menu with] at least two menu items, [and]

wherein the input device is used to select one menu item from amongst the at least two menu items,

wherein selection of one of the at least two menu items causes the display to show at least another one of the one or more screens that is a set screen including a plurality of control parameters associated with the selected menu item, and further wherein the set screen guides the individual through sequential steps for programming the plurality of control parameters associated with the selected menu item, and

wherein the input device is used to program the plurality of control parameters associated with the selected menu item from the set screen.

8. (Amended) An infusion system according to claim 1, [inlcuding] including a means to store a reservoir type that is programmable using the input device.

9. (Amended) An infusion system according to claim 1, [including a means] wherein selection of another one of the at least two menu items causes the infusion system to reset the control parameters to factory default values.

10. (Amended) An infusion system according to claim 1, [including a means] wherein selection of another one of the at least two menu items causes the infusion system to reset control parameters to values set by a health care professional.

12. (Amended) An infusion system according to claim 1, wherein selection of [at least] another one of the at least two menu items causes the drive mechanism to reverse direction.

13. (Amended) An infusion system according to claim 1, wherein selection of [at least] another one of the at least two menu items causes the infusion system to begin a selftest.

15. (Amended) An infusion system according to claim 1, wherein at least a further one of the one or more screens is a status screen.

16. (Amended) An infusion system according to claim 1, wherein selection of another one of the at least two menu items causes the display to show at least a further one of the one or more screens [includes one or more] that is a set screen[s] including a single control parameter associated with the selected menu item, and wherein the input device is used to program the single control parameter associated with the selected menu item from the set screen.

17. (Amended) An infusion system according to claim 16, wherein the [one or more set screens includes] selected menu item is a maximum basal rate [screen], and the single control parameter is a maximum rate at which units of fluid can be delivered during a basal delivery.

18. (Amended) An infusion system according to claim 16, wherein the [one or more set screens includes] selected menu item is a maximum bolus [screen], and the single control parameter is a maximum number of units of fluid that can be delivered in a single bolus delivery.

19. (Amended) An infusion system according to claim 1, wherein selection of another one of the at least two menu items causes the display to show at least a further one of the one or more screens [includes one or more] that is another select screen[s] including at least another two menu items associated with the selected menu item.

20. (Amended) An infusion system according to claim 19, wherein the [one or more] another select screen[s] includes a screen to select an insulin type.

21. (Amended) An infusion system according to claim 19, wherein the [one or more] another select screen[s] includes a screen to select a reservoir type.

22. (Amended) An infusion system according to claim 19, wherein the [one or more] another select screen[s] includes a screen to select a language.

27. (Amended) An infusion system according to claim 24, wherein selection of another one of the at least two menu items causes the display to show a further one or more of the one or more screens that include one or more information screens [is shown on the display screen] to guide the individual through [the] sequential steps to prime the infusion system.

28. (Amended) An infusion system according to claim 1, wherein one of the at least two menu items is highlighted by default when the [menu] select screen is initially displayed, and the menu item that is highlighted by default is dependent on a function that the infusion system is performing when the select screen is initially displayed.

29. (Amended) An infusion system according to claim 28, wherein the [one of at least two] menu item[s] that is highlighted by default when the [menu] select screen is initially displayed is a suspend command [dependent on a function that] if the infusion system is performing a bolus delivery when the [menu] select screen is initially displayed.

30. (Amended) An infusion system according to claim 1, further including a communication device for receiving communications from an external device to control the drive mechanism.

31. (Amended) An infusion system according to claim 30, wherein selection of [at least] another one of the at least two menu items causes the display to show a screen that allows [an] the individual [to signify the identity of a] to enter an identifier for the external device, which thereby configures the infusion system to accept communication from the external device.

42. (Amended) A method of programming an infusion device which includes a reservoir containing fluid for delivery into a user, a drive mechanism to force fluid from the reservoir, an input device that accepts inputs from the user, wherein the input device includes one or more keys including an escape key, a processor that uses control parameters to control the drive mechanism, wherein the control parameters may be changed through inputs from the user, and a display that receives information from the processor and visually displays screens containing the information for the user to see, the method comprising the steps of:

generating one or more menus;

accessing the one or more menus;

selecting a menu item from at least one of the one or more menus to access a set screen including a plurality of control parameters associated with the selected menu item, wherein the set screen guides the user through sequential steps for programming the plurality of control parameters associated with the selected menu item;

modifying [a] the plurality of control [parameter] parameters displayed on the set screen; and

either accepting the modification to the plurality of control [parameter] parameters and exiting the set screen, or pressing the escape key to exit the set screen without accepting the modification to the plurality of control [parameter] parameters.

43. (Amended) A programmable infusion device which includes a reservoir containing fluid for delivery into a user, a drive mechanism to force fluid from the reservoir, an input device

that accepts inputs from the user, wherein the input device includes one or more keys, a processor that uses control parameters to control the drive mechanism, wherein the control parameters may be changed through inputs from the user, and a display that receives information from the processor and visually displays screens containing the information for the user to see, the infusion device comprising:

generating means for generating one or more menus;

accessing means for accessing one or more menus;

selecting means for selecting a menu item from at least one of the one or more menus to access a set screen including a plurality of control parameters associated with the selected menu item, wherein the set screen guides the user through sequential steps for programming the plurality of control parameters associated with the selected menu item;

modifying means for modifying [a] the plurality of control [parameter] parameters displayed on the set screen;

accepting means for accepting the modification to the plurality of control [parameter] parameters and exiting the set screen; and

escape key means for exiting the set screen without accepting the modification to the plurality of control [parameter] parameters.

44. (Amended) An infusion system according to claim 19, wherein the [one or more] second select screen[s] includes a screen to select a therapy.

46. (Amended) An infusion system according to claim 1, wherein at least a further one of the one or more screens includes one or more confirmation screens.

-- 47. (New) An infusion system according to claim 1, wherein the selected menu item is a basal profile, and the set screen guides the individual through sequential steps for programming the plurality of control parameters associated with the basal profile. --

-- 48. (New) An infusion system according to claim 47, wherein the plurality of control parameters associated with the basal profile include a basal rate and a start time for the basal rate. --

-- 49. (New) An infusion system according to claim 1, wherein the selected menu item is a temporary basal profile, and the set screen guides the individual through sequential steps for programming the plurality of control parameters associated with the temporary basal profile. --

-- 50. (New) An infusion system according to claim 49, wherein the plurality of control parameters associated with the temporary basal profile include a basal rate and a duration for the basal rate. --

-- 51. (New) An infusion system according to claim 1, wherein the selected menu item is a square wave bolus, and the set screen guides the individual through sequential steps for programming the plurality of control parameters associated with the square wave bolus. --

-- 52. (New) An infusion system according to claim 51, wherein the plurality of control parameters associated with the square wave bolus include a bolus amount and a duration for delivering the bolus amount. --

-- 53. (New) An infusion system according to claim 1, wherein the selected menu item is a dual wave bolus, and the set screen guides the individual through sequential steps for programming the plurality of control parameters associated with the dual wave bolus. --

-- 54. (New) An infusion system according to claim 53, wherein the plurality of control parameters associated with the dual wave bolus include an immediate bolus amount, a square wave bolus amount, and a duration for delivering the square wave bolus amount. --